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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,106	10/31/2003	Stephane Caron	PC 23300A	1869

7590 01/31/2005

Warner-Lambert Company LLC
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER

PAVIGLIANITI, ANTHONY JOSEPH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,106

Applicant(s)

CARON ET AL.

Examiner

Anthony J. Paviglianiti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are ~~allowed~~ *allowable over the art of record*.
- 6) ☒ Claim(s) 1,2,6-12 is/are rejected.
- 7) ☒ Claim(s) 3-5 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1 – 14 are currently pending in the application.

Priority

This application claims benefit of priority to Provisional Application 60/423,328, filed November 1, 2002.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, **Claim 1** recites, “A *single-step* or multi-step process for the preparation of a compound of formula (XI)...” [emphasis added]. However, there is no definition or example in the original disclosure showing preparation of the compound of formula (XI) by a “single-step” process, nor is there a citation to a published reference to this end. Therefore the original disclosure does not convey to one of ordinary skill in the art that the inventor had possession of the claimed invention [in a “single-step” process] at the time of filing, and **Claim 1** thereby fails to comply with the written description requirement of 35 U.S.C. §112.

This rejection would be obviated by deleting the words “single-step or” from **Claim 1**.

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Claim 12 is rejected under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, **Claim 12** recites, “A process for the preparation of a compound of formula (XI), as defined in claim 1, or a stereoisomer thereof, comprising the *reductive amination* of a compound of formula (X)...” [emphasis added]. This appears to be an alternate method for “Step 8” in Scheme 2 (Specification at p. 12) to “reductive alkylation” recited in **Claim 11**. However, the specific method or reagents used for “reductive amination” of a compound of formula (X) are neither defined nor disclosed in the claim or the Specification, nor is there a citation to a published reference. Therefore the original disclosure does not convey to one of ordinary skill in the art that the inventor had possession of the claimed invention at the time of filing, and **Claim 12** fails to comply with the written description requirement of 35 U.S.C. §112.

Deleting **Claim 12** would obviate this rejection.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. §112, 2nd paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The relevant portion of **Claim 1** recites, “A single-step or multi-step process for the preparation of a compound of formula (XI) ... comprising a step in which the N-Ar² bond is constructed by a copper-mediated aryl amination.”

The omitted essential steps include the preparation of intermediate compounds of formula (IV), (V), (VI), (VII), (VIII), (IX), and (X), as described in **Claims 2 – 11**, and of the final product [formula (XI)] as described in **Claims 11 and 12**. See also Specification at page 11 (“Scheme 1”) and page 12 (“Scheme 2”). The essential step of preparing the intermediate compound of formula (II) was likewise omitted.

Claims 2, 6, 7, 8, 9, 10 and 11 are rejected under 35 U.S.C. §112, 2nd paragraph, for an insufficient antecedent basis in **Claim 1** for the limitations in each of these dependent claims. **Claims 2, 6, 7, 8, 9, 10 and 11** each recite the limitation, “A process *as claimed in claim 1* wherein a compound of formula [in order of appearance] (IV), (V), (VI), (VII), (IX), (X)...” [emphasis added], respectively. However, the independent claim, **Claim 1**, does not recite or describe any of the compounds of formula (IV), (V), (VI), (VII), (IX), or (X).

Specifically, the following recitations in dependent **Claims 2, 6, 7, 8, 9, 10 and 11** are without sufficient antecedent basis in **Claim 1**:

- 1) **[Claim 2]** “compound of formula (IV),” “compound of formula (II),” “compound of formula (III),” and “...in the presence of a cuprous salt, an amino ligand and a base”;
- 2) **[Claim 6]** “compound of formula (V),” “compound of formula (IV)” and “...a base in the presence of water”;
- 3) **[Claim 7]** “compound of formula (VI),” “compound of formula (V)” and “...with a thionyl halide”;
- 4) **[Claim 8]** “compound of formula (VII),” “compound of formula (VI)”;

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- 5) [Claim 9] “compound of formula (IX)” “compound of formula (VII),”
“compound of formula (VIII)”;
- 6) [Claim 10] “compound of formula (X),” “...by hydrolytically cleaving the –
SO₃H group...” and “compound of formula (IX)”;
- 7) [Claim 11] “compound of formula (X).”

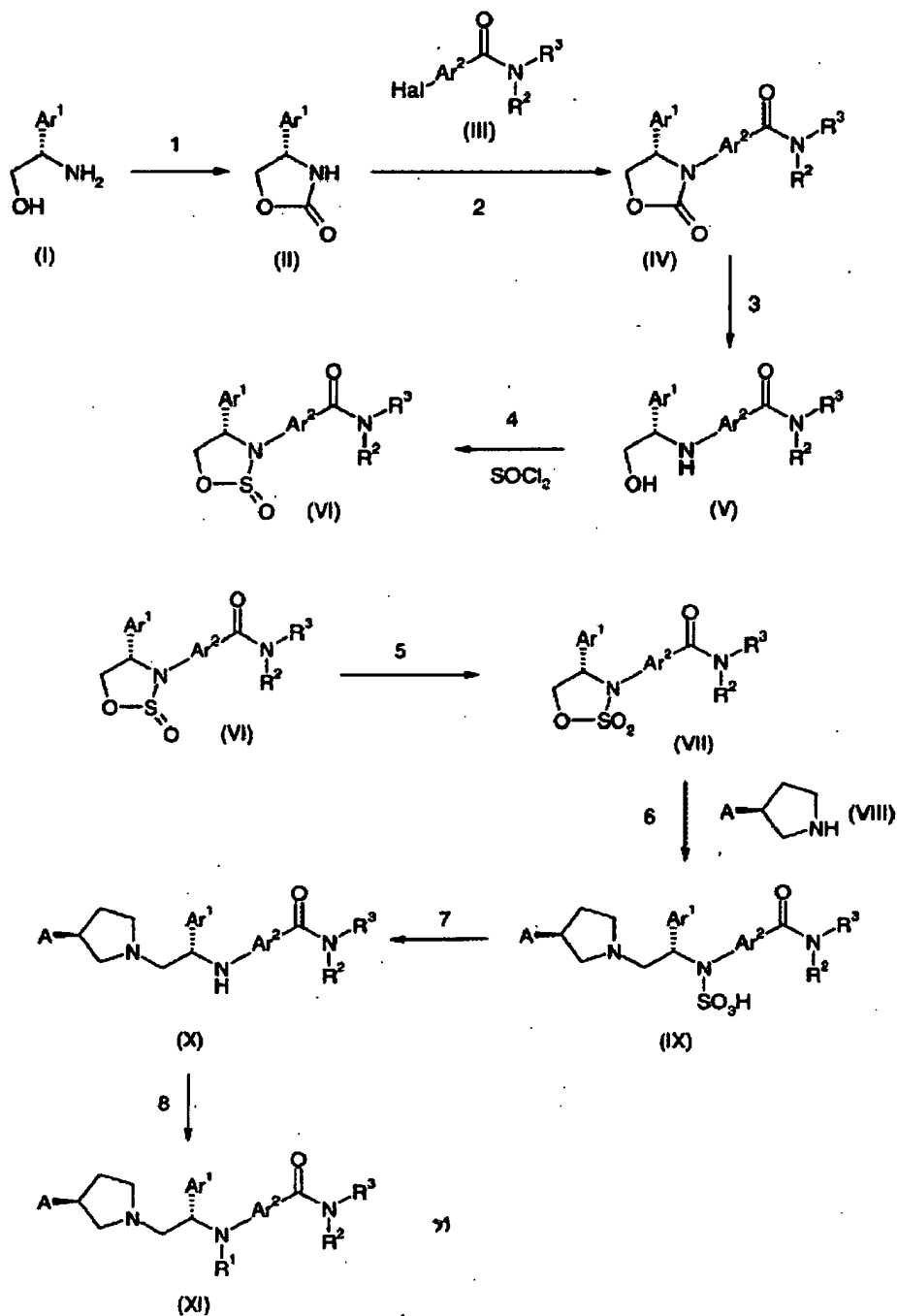
The rejections to Claim 1 and to dependent Claims 2, 6, 7, 8, 9, 10 and 11 would be obviated by reciting a written description of the essential process steps in the claim itself, after the transitional phrase “comprising” at the end of Claim 1, as follows:

[Claim 1] “ ...comprising the following steps:

- (a) treating a compound of formula (I) with a C₁-C₆ dialkyl carbonate in the presence of a base;
- (b) treating a compound of formula (II) with a compound of formula (III) in the presence of a cuprous salt, an amino ligand, and a base to construct the N-Ar² bond by a copper-mediated aryl amination;
- (c) treating a compound of formula (IV) with a base in the presence of water;
- (d) treating a compound of formula (V) with a thionyl halide, selected from SOCl₂ or SOBr₂;
- (e) treating a compound of formula (VI) with an oxidizing mixture comprised of a compound selected from RuCl₃, RuBr₃ or RuI₃, and hydrates thereof, and a compound selected from NaIO₄, NaOCl, or KIO₄;
- (f) treating a compound of formula (VII) with a compound of formula (VIII);
- (g) treating a compound of formula (IX) with a strong acid; and

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(h) treating a compound of formula (X) with an aldehyde alkylating agent and a boron hydride reducing agent; according to the following reaction diagram, where formulas (I), (II), (III), (IV), (V), (VI), (VII), (VIII), (IX), (X) and (XI) are defined below:



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Including the structures of each of the intermediate compounds of formulas (II) – (X), as above, would obviate the rejections made on the basis of lack of antecedent basis.

Claim Objections

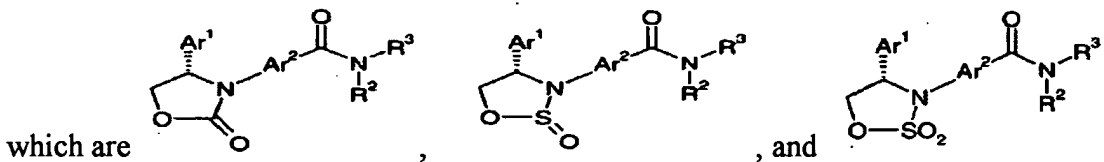
Claims 3 – 5 are objected to as being dependent upon a rejected base claim, **Claim 2**. See MPEP §608.01(n)(V). The objection to **Claims 3 – 5** would be obviated if the rejections to **Claim 2** and its independent claim, **Claim 1**, are resolved as described above.

Claim 13 objected to under 37 CFR §1.75 as being a substantial duplicate of **Claim 2**. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Specifically, **Claim 13** recites the identical substantive steps as were claimed in **Claim 2**, except that **Claim 13** is drafted so the process was *not* dependent upon **Claim 1** [the claim does, however, incorporate the definitions of “Ar¹, Ar², R², and R³” from **Claim 1**]. **Claim 2** recites, “A process as claimed in claim 1 wherein a compound of formula (IV)...” while **Claim 13** recites, “A process for the preparation of a compound of formula (IV)...” In addition, **Claim 13** also uses the transitional phrase “comprising,” which is not found in **Claim 2**; however, all of the substantive steps are identical between the two claims.

The objection to **Claim 13** would be obviated by deleting the claim.

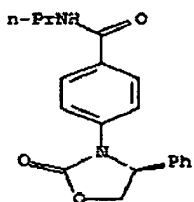
Analysis of Claim 14

Claim 14, which claims the intermediate *compounds* of formula (IV), (VI) and (VII),

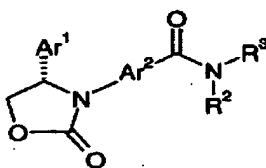


respectively, appears to be free of the prior art.

No prior art was found describing compounds of formula (IV), (VI), or (VII) in **Claim 14** above. The closest art describing any of the three claimed compounds in **Claim 14** is described in Ghosh, A., Sieser, J., Riou, M., Cai, W., and Rivera-Ruiz, L., "Palladium-Catalyzed Synthesis of N-Aryloxazolidinones from Aryl Chlorides," Organic Letters, vol. 5(13), pages 2207-2210 (June 26, 2003), which disclosed the synthesis of a compound with the structure:



(See Ghosh at p. 2209, compound 23 in Table 2), which would be a species



within the genus of formula (IV), , disclosed in **Claim 14** above; however, the Ghosh reference was published on the American Chemical Society Web site on May 24, 2003, which was after the filing date for Provisional Application 60/423,328 (November 1, 2002), which had disclosed the compounds of formula (VII), (VI), and (IV) on page 3, line 22, page 4, line 8, and page 5, line 1, respectively.

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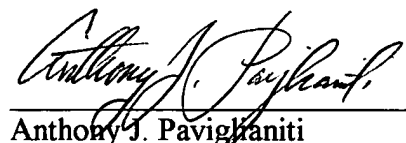
Conclusion

Claims 1, 2, and 6 – 12 are rejected. **Claims 3 - 5** are objected to as based on a rejected claim. **Claim 13** is objected to as a substantial duplicate of **Claim 2**. **Claim 14** appears to be free of the prior art.

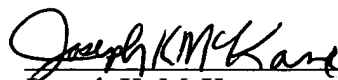
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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